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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,074	12/03/2003	Robert W. Stadler	P-20485.00	4895
27581	7590	06/09/2009		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER ALTER, ALYSSA MARGO	
			ART UNIT	PAPER NUMBER
			3762	
			MAIL DATE	DELIVERY MODE
			06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/727,074

Applicant(s)

STADLER ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-10, 13, 14, 16-26, 29, 30, 32, 34-36, 38-43, 46, 49, 50, 52-57 and 59-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 14, 16-26, 29, 30, 32, 34-36, 38-43, 46, 49, 50, 52-57 and 59-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2009 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-10, 13-14, 16-26, 29-30, 32, 34-36, 38-43, 46, 49-50, 52-57 and 59-63 have been considered but are not persuasive.

Claims 1, 4, 14, 17, 20, 30, 34 and 50 recite the limitation "ONE of" pressure, heart rate variability or activity level, but then in the last 9 lines of the independent claim includes the employment of each parameter coordinating to a different variable. This limitation to be satisfied, only one of the parameters is needed to be employed in the system, not all of the parameters. Therefore, since only "ONE of" pressure, heart rate variability or activity is selected, only one of the coordinating variables is employed. Therefore, the selected variables relations to the other unselected parameters variables are immaterial (and are relevant and are not even in the claim). Therefore, the pending claims remain rejected under *Hautala et al.*

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-10, 13-14, 16-26, 29-30, 32-43, 46-47 and 49-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of copending Application No. 10/727,008 (US Patent Application 20040172080 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because intrathoracic electrical impedance is a physiological parameter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 4, 14, 17, 20, 30, 34 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation a "means for updating" all three parameters (pressure, heart rate variability or activity level) and variables which was not previously described in the specification.

Furthermore, paragraph 66 of specification in the pre-grant publication discloses the use of FIVE variables (A-E) are employed not just ONE variable as presently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-10, 13-14, 16-26, 29-30, 32, 34-43, 46, 49-50, 52-57 and 59-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim 1 recites the limitation "ONE of" pressure, heart rate variability or activity level, but then in the last 9 lines of the independent claim includes the employment of each parameter. This is unclear since there is only antecedent basis for one of the parameters to be employed in the system, not all of the parameters. Furthermore, the employment of a variable is vague and unclear.

Additionally, the Applicant claims "a means for updating" however it is unclear what the Applicant considers this "means" to be. The Examiner is requiring (under 37 CFR 1.75) the Applicant specifically point out and specifically indicate in the specification where the "means" is described.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-10, 13-14, 16-26, 29-30, 32, 34-43, 46, 49-50, 52-57 and 59-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Hautala et al. (US Patent Publication 20010027266 A1). Hautala et al. discloses a heart rate measuring device. As Hautala et al. discloses on page 1, paragraph 9, "an anaerobic threshold value, i.e. the threshold value of heart rate, is found on the basis of changes in heart rate variation. Here heart rate variation means temporal variations in heart beats around the expected moments at which the heart should beat. In a preferred embodiment, the variation is calculated as moving standard deviation, but it, can also be calculated by another prior art mathematical method, e.g. by a method which utilizes the distribution function between the heart rate and the heart rate variation. As a function of heart rate, the heart rate variation naturally decreases as the heart rate, i.e. the heart beat frequency, increases. FIG. 1 illustrates variation as a function 100 of heart rate, i.e. the x axis 104 shows the heart rate as per cent of the maximum heart rate and the y axis 102 shows

standard deviation as milliseconds around the expected moment at which the heart should beat. FIG. 1 illustrates dependency between the heart rate variation and the heart rate, which applies to the majority of people. When the heart rate level is e.g. 40% of the maximum heart rate, the heart rate variation is between 15 to 25 milliseconds. The maximum heart rate means the heart rate value that can be calculated e.g. by the formula $(220 - \text{age})$, in which case the maximum heart rate of a 40-year old person is 180. The maximum heart rate can also be measured at the maximal workload or determined from the person's physiological properties using a neural network, for instance. It can be seen from FIG. 1 that as the heart rate level approaches the maximum heart rate, the heart rate variation decreases considerably". The examiner considers the moving standard deviation to be representative of the adaptive baseline trend.

Additionally, since Hautala et al. discloses the physiologic parameter of heart rate variability or activity. This limitation to be satisfied, only one of the parameters is needed to be employed in the system, not all of the parameters. Therefore, since only "ONE of" pressure, heart rate variability or activity is selected, only one of the coordinating variables is employed. Therefore, the selected variables relations to the other unselected parameters variables are immaterial. Furthermore, the examiner considers the variable to be the value of 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762